



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,845	05/29/2001	Chaitan Khosla	300622005500	7453
82359	7590	01/06/2009	EXAMINER	
Bristol-Myers Squibb Company c/o MoFo 12531 High Bluff Drive, Ste. 100 San Diego, CA 92130			ZHOU, SHUBO	
			ART UNIT	PAPER NUMBER
			1631	
			MAIL DATE	DELIVERY MODE
			01/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/867,845	KHOSLA ET AL.	
	Examiner	Art Unit	
	SHUBO (Joe) ZHOU	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 September 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 14-19 and 21-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/8/08.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

Applicant's amendment and request for reconsideration filed 9/29/08 are acknowledged and the amendment is entered.

Claims 14-19 and 21-24 are currently pending and under consideration.

Withdrawn Rejections/Objections

The objection to the disclosure is withdrawn in view of the amendments to the specification filed 9/29/08 and 2/8/08, respectively.

The rejection of claims 14-22 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and the rejection of the claims under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons set forth in the previous Office action mailed 11/30/06, are withdrawn in view of the extensive amendment to the claims filed 2/8/08.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14-19 and 21-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The rejection is necessitated by applicant's amendment to the claims filed 2/8/08 and recent court decisions on patent subject matter eligibility.

Claims 14-17, 19, and 21-23 are amended to be drawn to a method of designing a PKS gene comprising:

- (a) defining the structure of the desired polyketide by a first string of alphanumeric symbols, wherein each symbol in the first string represents a monomer unit of the polyketide,
- (b) comparing the first string of alphanumeric symbols to a second string of alphanumeric symbols from a database, wherein the database comprises at least one second string of alphanumeric symbols representing a known polyketide, and wherein each alphanumeric symbol in the second string represents a monomer unit of the known polyketide and also represents a polyketide module of the polyketide synthase,
- (c) identifying a common alphanumeric symbol or continuous sequence of alphanumeric symbols in said first and second strings,
- (d) generating an alignment, wherein the alignment consists of a combination of common alphanumeric symbols identified from the database such that the sequence of alphanumeric symbols in the alignment matches the first string, and wherein the alignment represents the structure of a new PKS gene capable of producing the desired polyketide, and
- (e) storing or displaying the alignment; or repeating steps (b) and (c).

The following analyses follow the rationales suggested in the Office's guidance to examiners under the Memorandum "Clarification of 'processes' under 35 USC § 101"

(published May 15, 2008, available online

www.uspto.gov/web/patents/memorandum.htm) and the "Interim Guidelines for

Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices:

22 November 2005, available from the US PTO website at

<http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>), which is

incorporated in the MPEP 2106.IV.C.2. Both are based on recent court decisions on patent subject matter eligibility.

Paragraph three of the Memorandum states:

"Based on Supreme Court precedent¹ and recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing.² If neither of these requirements is met by the claim, the method is not a patent eligible process under §101 and should be rejected as being directed to nonstatutory subject matter."

The methods of the instant claims are not tied to another statutory class (such as a particular apparatus or machine). Nominal or token recitations will not suffice, e.g. displaying, inputting, obtaining, etc. See *ex parte Langemyr*; Appeal 2008-1495, decided May 28, 2008. Reciting another statutory class in the preamble does not make the invention tie to the statutory class. Furthermore, in the instant invention, there is no physical transformation because a process of designing a PKS gene, *per se*, i.e. without actually synthesizing the gene, does not transform an article or physical subject to a different state or thing. Therefore, at least one embodiment of the claimed method is not a statutory process.

Additionally, the Guidelines states:

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- *The claimed invention "transforms" an article or physical object to a different state or thing.*
- *The claimed invention otherwise produces a useful, concrete and tangible result.*

In the instant claims, there is no physical transformation for reasons set forth above.

In the instant case, the invention does not produce a useful, concrete and tangible result. Specifically it does not produce a tangible result. The last steps of the claims, e.g. claim 1, are amended to recite storing or displaying the alignment representing the structure of a new PKS gene; or repeating steps (b) and (c), i.e. the steps of “comparing” and “identifying,” meaning that, at least for one embodiment, the step of “storing or displaying” is optional. For this very embodiment without the storing or displaying step, the claimed method does not produce a tangible result because the produced alignment representing the structure of the designed PKS gene would not be available to a user.

With regard to claim 18, drawn to a computer readable medium embodying a computer program for executing the method of claims 14, etc., since the method process of claim 14, etc. does not produce a useful, concrete and tangible result for reasons set forth above, the computer readable medium comprising a program for the method does not produce a useful, concrete and tangible result for the same reasons.

Furthermore, while the instant specification does not explicitly define the scope of the limitation of “computer readable medium,” one skilled in the art would understand

that computer readable medium includes carrier wave, which is a signal. For example, Fiekowsky et al., in US patent 6,090,555 (Date of Patent: July 18, 2000), define computer readable medium as being “a CD-ROM, floppy disk, tape, flash memory, system memory, hard drive, and a data signal embodied in a carrier wave.” See column 14, claim 12. Bornstein et al., in US patent 6,1443,88 (Date of patent : Nov. 7, 2000) state, “The computer readable medium of the present invention generally includes a tape, a floppy disk, a CD ROM, a carrier wave. In a preferred embodiment, however, the computer readable medium of the present invention is a carrier wave.” See column 8, lines 33-37.

Therefore, at least one embodiment of the instant claim * is drawn to carrier wave or a signal encoded thereon a computer program.

It was held by the court that claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage, or the strength of a magnetic field, define energy or magnetism, *per se*, and as such, are nonstatutory natural phenomena. O'Reilly, 56 U.S. (15 How.) at 112-14. Moreover, it does not appear that a claim reciting a signal encoded with functional descriptive material, e.g. a computer program, falls within any of the categories of patentable subject matter set forth in § 101. The following analysis on why such a signal encoded with functional descriptive material is nonstatutory subject matter is excerpted from the US PTO's "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility:"

First, a claimed signal is clearly not a “process” under § 101 because it is not a series of steps. The other three § 101 classes of machine, compositions of matter and manufactures “relate to structural entities and can be grouped as ‘product’ claims in order to contrast them with process claims.” 1 D. Chisum, Patents §1.02 (1994). The three product classes have traditionally required physical structure or material.

“The term machine includes every mechanical device or combination of mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result.” Corning v. Burden, 56 U.S. (15 How.) 252, 267 (1854). A modern definition of machine would no doubt include electronic devices which perform functions. Indeed, devices such as flip-flops and computers are referred to in computer science as sequential machines. A claimed signal has no physical structure, does not itself perform any useful, concrete and tangible result and, thus, does not fit within the definition of a machine.

A “composition of matter” “covers all compositions of two or more substances and includes all composite articles, whether they be results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.” Shell Development Co. v. Watson, 149 F. Supp. 279, 280, 113 USPQ 265, 266 (D.D.C. 1957), aff’d, 252 F.2d 861, 116 USPQ 428 (D.C. Cir. 1958). A claimed signal is not matter, but a form of energy, and therefore is not a composition of matter.

The Supreme Court has read the term “manufacture” in accordance with its dictionary definition to mean ‘the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.’ Diamond v. Chakrabarty, 447 U.S. 303, 308, 206 USPQ 193, 196-97 (1980) (quoting American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11, 8 USPQ 131, 133 (1931), which, in turn, quotes the Century Dictionary). Other courts have applied similar definitions. See American Disappearing Bed Co. v. Arnaelsteen, 182 F. 324, 325 (9th Cir. 1910), cert. denied, 220 U.S. 622 (1911). These definitions require physical substance, which a claimed signal does not have. Congress can be presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change. Lorillard v. Pons, 434 U.S. 575, 580 (1978). Thus, Congress must be presumed to have been aware of the interpretation of manufacture in American Fruit Growers when it passed the 1952 Patent Act.

*A manufacture is also defined as the residual class of product. 1 Chisum, § 1.02[3] (citing W. Robinson, *The Law of Patents for Useful Inventions* 270 (1890)). A product is a tangible physical article or object, some form of matter, which a signal is not. That the other two product classes, machine and composition of matter, require physical matter is evidence that a manufacture was also intended to require physical matter. A signal, a form of energy, does not fall within either of the two definitions of manufacture. Thus, a signal does not fall within one of the four statutory classes of § 101.*

[.....]

These interim guidelines propose that such signal claims are ineligible for patent protection because they do not fall within any of the four statutory classes of § 101. Public comment is sought for further evaluation of this question.

Thus, claim 18 is drawn to nonstatutory subject matter.

With regard to claim 24, drawn to an alignment representing the structure of the designed PKS gene, the claim is drawn to nonstatutory subject matter because an alignment is nonfunctional descriptive material. See also MPEP 2106 IV (B) (1).

Claim Rejections-35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-19 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 14, 18, and 19 are amended to recite “wherein the database comprises at least one second string of alphanumeric symbols representing a known polyketide, and wherein each alphanumeric symbol in the second string represents a monomer unit of the known polyketide and also represents a polyketide module of the

polyketide synthase.” A review of the specification reveals that it discloses neither that each alphanumeric symbol in the second string in a database represents a monomer unit of a known polyketide, nor that the each alphanumeric symbol also represents a polyketide molecule of a PKS gene.

Independent claims 14, 18, and 19 are also amended to recite “generating an alignment, wherein the alignment consists of a combination of common alphanumeric symbols identified from the database such that the sequence of alphanumeric symbols in the alignment matches the first string, and wherein the alignment represents the structure of a new PKS gene capable of producing the desired polyketide.” The Office could not find adequate support therefor in the specification for such an alignment that consists of a combination of common alphanumeric symbols identified from the database such that the sequence of alphanumeric symbols in the alignment matches the first string, and wherein the alignment represents the structure of a new PKS gene capable of producing the desired polyketide.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

Art Unit: 1631

(EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/SHUBO (Joe) ZHOU/

Shubo (Joe) Zhou, Ph.D.

Primary Examiner

Art Unit 1631